IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MELINDA KILLEN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 11-1508
	)	
STRYKER SPINE, an unincorporated division of Howmedica Osteonics Corporation,	)	Judge Joy Flowers Conti Magistrate Judge Maureen P. Kelly
	)	
Defendant.	)	

MEMORANDUM ORDER

This action was removed from the Court of Common Pleas of Allegheny County to this court on November 28, 2011. [ECF No. 1]. In the complaint, plaintiff Melinda Killen ("Plaintiff") asserts claims arising from the surgical implantation of the CerviCore Intervertebral Device ("Cervicore") and seeks damages for the injuries that she sustained as a result of the artificial disc implant. The case was referred to a United States Magistrate Judge for pretrial proceedings in accordance with the Magistrate Judges Act, 28 U.S.C. § 636(b)(1), and Local Rules of Court 72.C and 72.D.

Defendant Stryker Spine ("Defendant") filed a motion to dismiss. [ECF No. 3]. Plaintiff filed a response in opposition. [ECF No. 11]. A reply and sur-reply were also filed. [ECF Nos. 14, 20].

The magistrate judge's report and recommendation, filed on August 21, 2012, recommended that the motion to dismiss filed by Defendant, and premised upon federal preemption, be granted in part and denied in part [ECF No. 22]. Service of the Report and

Recommendation was made upon all counsel of record. The parties were informed that in accordance with the Magistrate Judge's Act, 28 U.S.C. § 636(b)(1)(B) and (C), and Rule 72.D.2 of the Local Rules of Court, that they had fourteen days to file any objections. Defendant filed objections to the Report and Recommendations (the "objections") on September 7, 2012. [ECF No. 23]. Plaintiff filed a reply to the pobjections (the "reply") on September 21, 2012. [ECF No. 27].

Defendant asserts five specific objections upon which it argues that this court should reject the recommendations of the magistrate judge, grant the motion to dismiss, and dismiss Plaintiff's complaint in its entirety with prejudice. In her reply, Plaintiff requests that this court adopt the Report and Recommendation and deny the motion to dismiss.

After review of the complaint, the objections, the reply, the filings related to the motion to dismiss, applicable case law, and the Report and Recommendation, the court adopts the Report and Recommendation. Each of the five objections are addressed seriatim.

I. Objection that Plaintiff did not successfully pled parallel claims.

Defendant contends that Plaintiff did not successfully plead parallel claims on the ground that Current Good Manufacturing Practices ("CGMPs") are not applicable to investigational devices ("IDE devices") such as the CerviCore disc. Defendant is correct that CGMPs cannot serve as the basis for Plaintiff's state law claims because under 21 C.F.R. § 812.1, IDEs are exempt from CGMPs' requirements. See Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090, 1096 (6th Cir. 1997). If Plaintiff asserted her claims based on Defendant's violations of the CGMPs, those claims would be preempted because they would be different from or in addition to the requirements imposed by federal regulation. Id. at 1096. Plaintiff, however, does not rely on the CGMPs in the manner that Defendant suggests. Plaintiff alleges that Defendant violated the

requirements imposed on Defendant by the FDA in the IDE approval process and relies on the CGMPs to set forth a plausible claim of what those requirements were. (ECF No. 28 at 4-5.) Plaintiff alleges that before discovery, she cannot determine what requirements the FDA actually imposed on defendant in the IDE approval process because that information is confidential. The court finds that state law claims asserting parallel violations of the requirements imposed by the FDA during the IDE approval process are not preempted because they are not different from or in addition to federal requirements or regulations. Plaintiff's claims, therefore, are not preempted to the extent that requirements imposed by the FDA on Defendant during the IDE approval process were the same as the requirements imposed by the CGMPs. To the extent the requirements imposed by the FDA in the IDE approval process are different from or in addition to the CGMP requirements, however, plaintiff's claims referring to those CGMP requirements will be preempted.

Defendant also argues that to the extent Plaintiff relies upon 21 C.F.R. § 812.5, the regulation is not device specific and Plaintiff's claim alleging the violation of § 812.5 is preempted. Defendant further contends that specific parallel claims must be asserted at this initial pleading stage. In response, Plaintiff argues that she sufficiently pled parallel claims to the best of her ability at this initial stage of the case. She further contends that prior to discovery it is impossible for her to access the device-specific requirements imposed by the Food and Drug Administration ("FDA"). Based on this sufficiency of pleading, Plaintiff argues that her negligence claims are not preempted. [ECF No. 28 at 2-5].

The court finds that the magistrate judge conducted a detailed and thorough review of this evolving area of the law relating to parallel claims and preemption, including the arguments raised again by Defendant in the objections. The magistrate judge also discussed the holding in

Gross v. Stryker, Civil No. 11-1229, 2012 WL 876719 (W.D. Pa. Mar. 14, 2012). While agreeing in substance with the legal rationale in Gross, the magistrate judge correctly recognized that the facts of this case are distinguishable from the facts in Gross. Here, Plaintiff sufficiently pled parallel claims at this initial stage of the proceedings.

Plaintiff specifically avers in her complaint that Defendant: (1) was negligent in its record keeping and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant and argues that this activity violated the manufacturer's duty to establish and maintain procedures for implementing corrective and preventative action – which are alleged requirements of the IDE approval process that are the same as those imposed under 21 C.F.R. § 800.100(a)(6)(7); (2) was negligent in compromising the integrity of the CerviCore implant by utilizing titanium coating techniques – which is a violation of the alleged requirements of the IDE approval process that are the same as those imposed under 21 C.F.R. § 820.70(e),(h)[1]; and, (3) failed to provide proper warnings concerning defects in the device, including the use of nickel and the risks of metallosis, in violation of a manufacturer's duty outlined in 21 C.F.R. § 812.5(a) to describe "all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions." As recognized in the Report and Recommendation, Plaintiff, in her sur-reply, refers to the allegation in the complaint that Defendant was negligent in performing metal allergy testing prior to accepting patients into the clinical trial, but admits that, without discovery, Plaintiff cannot identify specific requirements imposing such testing.

The magistrate judge correctly found that these descriptions of purported regulatory violations go beyond the rote conclusory pleadings that the Gross court found insufficient to

[1] The magistrate judge noted that this same regulation was construed in Howard v. Sulzer Orthopedics, Inc., 382 F. App'x 436, 440–41 (6th Cir. 2010), as a sufficient basis on which to base a parallel claim.

sustain parallel claim allegations.

As noted in the Report and Recommendation, it is disingenuous to identify the parallel claim exception to the Medical Device Act Amendments of 1976 ("MDA") exemption as articulated in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008) , but foreclose a plaintiff any opportunity to prove the exception. As recognized in Burgos v. Satiety, No. 10-CV-2680, 2011 WL 1327684 (E.D.N.Y. Apr. 5, 2011):

> [P]laintiffs alleging state-law parallel claims based on a violation of a manufacturer's agreement with the FDA often suffer from a unique disadvantage: the agreements (including IDEs) that would provide the necessary factual specificity are confidential, and available only to the defendants and the FDA. [A]plaintiff's pleading burden should be commensurate with the amount of information available to them. Other courts have similarly observed that it would be an injustice to penalize a plaintiff for alleging, through no fault of her own, what turned out to be insufficient facts about the manufacturing process of a device that caused injury. See Hofts v. Howmedica Osteonics Corp., 597 F. Supp.2d 830 (S.D. Ind. 2009); see also Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010).

Id. at *4 (citing In re Medtronic, Inc., Spring Fidelis Leads Products Liability Litigation, 623 F.3d 1200, 1209 (8th Cir. 2010) (Melloy, J., concurring in part and dissenting in part and noting injustice arising from court's decision to rigidly adhere to Twombly, rather than pragmatically evaluate the complaint in context of plaintiff's informational limitations)). Given the specific facts of this case where Plaintiff advanced factual allegations that plausibly suggest the existence of parallel claims, but does not have access to the confidential information to plead more specifically the alleged violation of FDA regulations, the court concludes the pleading standards are satisfied.

II. Objection that Plaintiff's strict liability claim is prohibited under Pennsylvania law.

Defendant argues that the magistrate judge erred in finding that while Pennsylvania law

prohibits strict liability claims in prescription medical device cases based on design defect and failure to warn, Pennsylvania law does not preclude strict liability claims alleging a manufacturing defect. Defendant contends that Plaintiff's complaint does not contain allegations sufficient to implicate manufacturing defect strict liability claims and, in any event, Pennsylvania law prohibits all strict liability claims in a medical device case.

Plaintiff responds that she properly alleged manufacturing defect strict liability claims. She contends that Pennsylvania law does not prohibit strict liability manufacturing defect claims and breach of implied warranty of merchantability claims for defective devices.

At the outset, this court finds that the magistrate judge correctly considered that Pennsylvania law recognizes three different strict liability claims: design defect, manufacturing defect and failure to warn. Phillips v. A-Best Products Co., 665 A.2d 1167, 1170 (Pa. 1995). The magistrate judge also recognized that in Hahn v. Richter, 673 A.2d 888 (Pa. 1996), the Pennsylvania Supreme Court decided that strict liability claims based upon a failure to warn theory cannot be brought against prescription drug manufacturers. The Pennsylvania Supreme Court relied upon and adopted comment k of Section 402A of the Restatement (Second) of Torts. As both parties acknowledge, the Pennsylvania Supreme Court has not addressed whether Hahn's rationale applies to medical device manufacturers. As such, the magistrate judge correctly identified the conflicting authority on this issue in decisions issued by panels of the Pennsylvania Superior Court and federal district courts in Pennsylvania.

This court concludes that the magistrate judge properly relied upon the rationale set forth in Dougherty v. C.R. Bard, Inc., C.A. No. 11-6048, 2012 WL 2940727 (E.D. Pa. July 18, 2012), where, after a thorough analysis of Hahn, the district judge found that while Hahn instructs that strict liability applies to failure warn claims, comment k's exemption from strict liability does

not extend to manufacturing defects. Id. at *6. At this preliminary stage of the litigation, Plaintiff's allegations in paragraph 48(a), (d), (i) and (j) of the complaint sufficiently allege a manufacturing defect claim in strict liability. Accordingly, the motion to dismiss with respect to the strict liability manufacturing claim in this case was properly denied.

III. Objection that Plaintiff's breach of implied warranty of merchantability claim is prohibited under Pennsylvania law.

Defendant contends that, as with strict liability, Plaintiff's breach of implied warranty of merchantability is prohibited under Pennsylvania law. Defendant points to the same reasons it asserts with respect to Objection II, as its basis to object to this recommendation. Defendant also claims that the implied warranty of merchantability does not apply to IDE devices.

This court concludes that the magistrate judge conducted a thorough review of the applicable case law and correctly relied on the rationale set forth in Dougherty, in determining that to the extent that Plaintiff's implied warranty claim is based on failure to warn or design defect, it is not cognizable under Pennsylvania law and must be dismissed. Because Plaintiff, however, alleged specific facts supporting a manufacturing defect in violation of FDA requirements for the IDE approval process which are the same as other requirements of pertinent federal regulations, Plaintiff will be permitted to amend her complaint as set forth in the recommendation.

IV. Objection that Plaintiff's express warranty claim is preempted.

Defendant concedes that the magistrate judge correctly found that Plaintiff's express warranty claim was insufficiently pled. Defendant, however, takes issue with the recommendation that Plaintiff should be allowed an opportunity to amend the complaint. It contends that an amendment would be futile.

Plaintiff argues that she should be permitted to amend her complaint to allege additional

details to support her breach of express warranty claim. Plaintiff points out that Pennsylvania law does not preclude express warranty claims against manufacturers of medical devices.

Having considered the objections and reply with respect to this issue, this court concludes that the magistrate judge conducted a detailed analysis about whether breach of express warranty claims are cognizable in the medical device context. The magistrate judge recognized that federal courts within Pennsylvania have split on this issue. As set forth in the Report and Recommendation, some courts have implicitly recognized express warranty claims as viable causes of action against manufacturers of prescription drugs and devices. See e.g. Kee v. Zimmer, Inc., No. 11-7789, 2012 WL 1758618, at *3 (E.D. Pa. May 17, 2012); Horsman, 2011 WL 5509420, at *3-4; Kester v. Zimmer Holdings, Inc., No. 2:10–cv–00523, 2010 WL 2696467, at *10–11 (W.D. Pa. June 16, 2010). Other courts, however, have held that Pennsylvania law precludes such express warranty claims. See, e.g., Aaron v. Wyeth, No. 07–0927, 2010 WL 653984, at *11 (W.D. Pa. Feb.19, 2010); Kline v. Pfizer, Inc., No. 08–3238, 2008 WL 4787577, at *3 (E.D. Pa. Oct. 31, 2008); Colacicco v. Apotex, Inc., 432 F. Supp.2d 514 (E.D. Pa.2006), *aff'd on other grounds*, 521 F.3d 253 (3d Cir. 2008), vacated 129 S. Ct. 1578 (2009). Based on this review, and in the context of this case, the magistrate judge properly determined that Pennsylvania law does not preclude express warranty claims against manufacturers of prescription drugs and devices, such as Defendant.

The magistrate judge correctly recognized that, at this point, Plaintiff's complaint does not sufficiently allege how or by whom a promise was made or what exactly was promised. Without factual allegations sufficient to describe a specific promise that became the basis of the bargain, or to show that the promise was directed at her, Plaintiff's express warranty claim may not escape dismissal. See Kester v. Zimmer Holdings, Inc., No. 2:10–cv–00523, 2010 WL

2696467, at *10–11 (W.D. Pa. June 16, 2010). Therefore, the motion to dismiss is granted with respect to count VI of the complaint, but the grant is without prejudice to Plaintiff being permitted to amend her complaint to allege sufficient detailed facts, if any, to support her breach of express warranty claim.

V. Objection that Plaintiff's fraud and misrepresentation claims are preempted and should be dismissed.

Defendant, in a brief objection, states that the magistrate judge correctly found that Plaintiff's claims of fraud misrepresentation are preempted to the extent that they take issue with Defendant's statements regarding testing, research, etc., as such claims challenge the sufficiency of FDA oversight and investigation. Defendant, however, objects to the magistrate judge allowing Plaintiff's fraud and misrepresentation claims to survive preemption based on Plaintiff's allegation that Defendant falsely represented that she would receive appropriate medical care. Defendant claims that representations regarding follow-up medical care fall within the purview of FDA regulation and are preempted by federal law.

Plaintiff contends that the magistrate judge correctly found that the MDA does not preempt Plaintiff's fraud and negligent misrepresentation claims because Defendant's false representations concern matters beyond the scope of the FDA's regulation of investigative devices.

In the Report and Recommendation, the magistrate judge conducted a review of MDA preemption and Pennsylvania law. The magistrate judge correctly recognized the distinction that Plaintiff's fraud and misrepresentation claims with respect to Defendant's declarations about testing, research and inspections are preempted in accordance with Riegel, 552 U.S. at 323. Plaintiff's claims with respect to representations of and fraud by Defendant with respect to follow-up care, however, are not within the scope of the applicable federal regulations and are

not preempted by the MDA, or by applicable Pennsylvania law. Accordingly, the recommendation with respect to count III is adopted.

AND NOW, this 28th day of September, 2012,

IT IS HEREBY ORDERED that the motion to dismiss is granted in part and denied in part as follows:

a. COUNT I – NEGLIGENCE. The motion to dismiss is denied with respect to Plaintiff's claim alleging negligence;

b. COUNT II – STRICT LIABILITY. The motion to dismiss is granted with respect to Plaintiff's strict liability design defect and failure to warn claims, but denied with respect to Plaintiff's strict liability manufacturing defect claim;

c. COUNT III – FRAUD. The motion to dismiss is granted with respect to Plaintiff's fraud claims arising out of Defendant's product literature and labeling, but denied with respect to claims arising out of Defendants' alleged intentional misrepresentations concerning Killen's medical care;

d. COUNT IV – NEGLIGENT MISREPRESENTATION. The motion to dismiss is granted with respect to Plaintiff's claim alleging negligent misrepresentations in product literature and labeling regarding the testing, research, and inspection of the CerviCore implant, but denied with respect to Plaintiff's claim arising out of Defendants' alleged negligent misrepresentations concerning Killen's medical care;

e. COUNT V – BREACH OF IMPLIED WARRANTIES. The motion to dismiss is granted with respect to Plaintiff's claim for breach of implied warranty of fitness for a particular purpose, but denied with respect to Plaintiff's claim for breach of implied warranty of merchantability;

f. COUNT VI – BREACH OF EXPRESS WARRANTIES. The motion to dismiss is granted with respect to Plaintiff's breach of express warranties claim, but the grant is without prejudice to Plaintiff being permitted to amend her complaint to allege sufficient detailed facts, if any, to support her claim of breach of express warranty;

g. COUNT VII – PUNTIVE DAMAGES. The motion to dismiss is denied with respect to Plaintiff's claim for punitive damages.

IT IS FURTHER ORDERED that the Report and Recommendation of Magistrate Judge Kelly, dated August 21, 2012, as supplemented or modified by this memorandum order, is adopted as the Opinion of the Court.

BY THE COURT,

/s/ Joy Flowers Conti
JOY FLOWERS CONTI
UNITED STATES DISTRICT JUDGE

cc: Maureen P. Kelly
United States Magistrate Judge